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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,677	09/14/2001	Christine Libon	PF95PCTSEQ/D	9128

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[REDACTED] EXAMINER

FIELD, TAMMY K

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1645

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/936,677	LIBON ET AL.
	Examiner	Art Unit
	Tammy K. Field	1645

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on September 21, 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 29-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 29-61 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

1. Claims 1-28 have been canceled. Claims 29-61 have been added and are presently under consideration.
2. Claims 29 -51 – It is noted that “use of” is not a statutory category of invention. For purposes of lack of unity, these claims have been interpreted as a method for the preparation of a membrane fraction. A response should be accompanied with amendment.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 29-44, 52-55, and 60-61 drawn to a method for preparation of a membrane fraction of gram-negative bacteria comprising proteoglycans.

Group II, claim(s) 45-51, and 56-59, drawn to methods of use for a pharmaceutical composition.

4. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of claim 1 is drawn to a method for preparation of a membrane fraction of gram-negative bacteria comprising proteoglycans. The art of d'Hinterland, *et al.*

(French Patent #2,596,064 published September 25, 1987) teaches methods for the manufacture of immunogenic microbial ribosomal fractions and membrane proteoglycans of *Klebsiella pneumoniae*: associated as adjuvants at page 3, paragraphs 1-3. More specifically, d'Hinterland, *et al.* teaches methods of obtaining membrane proteoglycans of *Klebsiella pneumoniae* from bacterial lysates at page 13, paragraph 2- page 14. d'Hinterland, *et al.* further teaches a preparation of pharmaceutical vaccines, *e.g.* membrane proteoglycans of *Klebsiella pneumoniae* combined with ribosome fractions of *Escherichia coli*, *Salmonella typhimurium*, *Shigella dysenteriae*, and *Staphlococcus aureus* at page 8, number 2. Therefore, Unity of Invention is not fulfilled because there is not a technical feature that is "special", in that the technical feature does not define a contribution over the art. As such, a method for preparation of a membrane fraction of gram-negative bacteria comprising proteoglycans lacks unity of invention.

Further in the instant case, the claims in Groups I and II recite different methods with different goals and therefore these methods also lack unity of invention because they lack a special technical feature in common within the meaning of PCT Rule 13.2.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Invention I

- A. cytokine (Claim 38)
- B. hormones (Claim 39)

- C. growth factors (Claim 40)
- D. cellular compound (Claim 41)
- E. DNAs (Claim 42)
- F. RNAs (Claim 42)
- G. ribosome family (Claim 43)
- H. heat shock protein family (Claim 44)

Invention II – Species 1

- I. chemotherapy (Claim 46)
- J. radiotherapy (Claim 46)
- K. protease inhibitor (Claim 49)
- L. compound with anti-angiogenic activity (Claim 49)

Invention II – Species 2

- M. bladder cancers (Claim 51)
- N. prostate cancers (Claim 51)
- O. colon cancers (Claim 51)
- P. liver cancers (Claim 51)
- Q. malignant melanomas (Claim 51)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. If applicants elect Invention I, they should also elect a single species as set forth supra. If applicants elect Invention II, they should also elect a single species each from species 1 and species 2 as set forth supra. The reply must also identify the claims readable on the elected species, including any claims subsequently

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added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner:
Invention I – claim(s) 29-44, 52-55, and 60-61, and Invention II – claim(s) 45-51, and 56-59.
The following claim(s) are generic: 29, 34, 52 and 53.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Invention I, claim 29 read on the technical feature for a preparation of a membrane fraction of gram-negative bacteria comprising proteoglycans. Through the teachings of d'Hinterland, *et al.* (French Patent #2,596,064 published September 25, 1987) Unity of Invention is not fulfilled because there is not a technical feature that is “special”, in that the technical feature does not define a contribution over the art. As such, a method for preparation of a membrane fraction of gram-negative bacteria comprising proteoglycans lacks unity of invention. Therefore, the species depending on generic claim 29 as set forth supra are also deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (703) 305-4447. The examiner can normally be reached 7am-4:30pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Tammy K. Field

September 22, 2003

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LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER